

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X

UNITED STATES OF AMERICA,

- against -

PETER J. RICCIO,
LENA LASHER a/k/a Lena Contang,
JOHN NICHOLAS BURLING,
ROBERT P. IMBERNINO,
EDMOND S. KAPLAN,
TIMOTHY KEAR,
CHRISTOPHER RILEY,
ADAM RISOLIA,
GERGANA CHERVENKOVA, and
PAUL GRYSZKIEWICZ,

12 CR 868 (NRB)

MEMORANDUM AND ORDER

Defendants.

-----X

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

BACKGROUND

On November 20, 2012, ten defendants were charged in a seven-count indictment (the "Indictment") for crimes in connection with their alleged participation in an internet pharmacy scheme. According to the Indictment, the allegations of which we accept as true for purposes of the present motion, United States v. Goldberg, 756 F.2d 949, 950 (2d Cir. 1985), the defendants acted in concert to dispense prescription drugs over the Internet to customers who had never seen or spoken to a physician or medical practitioner. Indictment ¶ 5.

Specifically, the internet pharmacy scheme enabled customers to visit one of several prescription websites operated by certain co-defendants and select the prescription drugs they wished to order. Id. Customers would then be prompted to complete an online questionnaire regarding medical history, often with answers prepopulated such that the customers would not be disqualified from receiving the prescription drugs they had selected. Id. The website operators electronically sent completed questionnaires to doctors, who issued prescriptions for the drugs requested by the customers without first conducting an in-person medical examination or telephonic consultation with the customers, or otherwise verifying any of the information provided by the customers. Id. The website operators then electronically sent those prescriptions to pharmacists, who filled the prescriptions and mailed the orders to the customers. Id.

The Indictment charges the following crimes arising from this scheme: (1) narcotics conspiracy in violation of 21 U.S.C. § 846, (2) distribution of narcotics in violation of 21 U.S.C. § 841, (3) conspiracy to misbrand in violation of 18 U.S.C. § 371, (4) substantive misbranding in violation of 21 U.S.C. § 331(a), 333(a)(2), and 353(b), (5) conspiracy to commit mail and wire fraud in violation of 18 U.S.C. § 1349, (6) conspiracy to commit international money laundering in violation of 18 U.S.C. §

1956(h), and (7) conspiracy to commit domestic money laundering in violation of 18 U.S.C. § 1956(h).¹

To date, eight of the ten defendants have entered pleas of guilty, and one defendant, Gergana Chervenкова, is living abroad beyond the scope of U.S. jurisdiction. The remaining defendant, Lena Lasher ("defendant"), has entered a plea of not guilty. The Indictment charges that defendant Lasher, while employed as a pharmacist in an establishment owned and operated by co-defendant Peter Riccio, participated in the internet pharmacy scheme, and thereby committed each of the seven counts charged.

Defendant Lasher now brings the pending motion to dismiss the Indictment on the grounds that each of the counts charged therein fails to state an offense. She also moves to strike surplusage from the Indictment. For the reasons set forth below, we deny defendant's motion to dismiss the Indictment and reserve on her motion to strike surplusage from the Indictment.

DISCUSSION

I. Legal Standard

The issue of whether the Indictment is legally sufficient is addressed in a well-established context. An indictment "need do little more than to track the language of the statute charged and state the time and place (in approximate terms) of the alleged crime." United States v. Stringer, 730 F.3d 120, 124

¹ The Indictment also includes forfeiture allegations. Indictment ¶¶ 34-38.

(2d Cir. 2013) (internal citation and quotation marks omitted). "[A]n indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and second, enables him to plead an acquittal or conviction in bar of future prosecutions." Hamling v. United States, 418 U.S. 87, 117 (1974) (citations omitted). Indeed, Federal Rule of Criminal Procedure 7(c) merely requires that an Indictment contain "a plain, concise, and definite written statement of the essential facts constituting the offense charged."

II. Counts One and Two: Narcotics Offenses Adequately Alleged

Counts One and Two of the Indictment charge Lasher with conspiracy to deliver, distribute and dispense controlled substances, and substantive delivery, distribution and dispensation of controlled substances, respectively, in violation of the Controlled Substances Act. Indictment ¶¶ 8-10, 13-14. Specifically, the Indictment alleges that Lasher dispensed Fioricet, a combination drug containing the schedule III controlled substance Butalbital, in violation of 21 U.S.C. § 841(b)(1)(E) and 21 U.S.C. § 841(h). Indictment ¶¶ 4-6, 14.

The applicable statute unambiguously defines as a controlled substance "[a]ny substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid." 21 U.S.C. § 812, Schedule III,

Part (b)(1). Because Fioricet contains Butalbital, a derivative of barbituric acid, there is no dispute that Fioricet falls within the category of drugs controlled by 21 U.S.C. § 812. See Def. Mem. at 4-5; Def. Reply Mem. at 2. As a Schedule III controlled substance, Fioricet is then subject to the statute charged in Counts One and Two, 21 U.S.C. § 841(h), which criminalizes the dispensation of controlled substances by means of the internet. Specifically, section 841(h) provides as an example of such criminal activity the "offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire" This is the very conduct alleged against Lasher in the Indictment.

Thus far, the parties are in agreement. See Def. Mem. at 4-5; Gov't Opp. at 5-9, Def. Reply Mem. at 2; Tr. at 10-13. The dispute arises because of a regulation promulgated by the Drug Enforcement Agency, a delegatee of the Attorney General's statutory authorization to "exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part" of Subchapter I of the Controlled Substances Act. 21 U.S.C. § 811(g). The regulation classifies Fioricet as an "exempted prescription product" which has "been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, and 1002 through 1004

of the Act (21 U.S.C. 822-825, 827-829, and 952-954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only." 21 C.F.R. § 1308.32.

Defendant contends that the regulatory exemption renders Fioricet a non-controlled substance for the purposes of the criminal statutes charged in the Indictment. Def. Mem. at 9-12. Based on its plain language, as well as the relevant statutory and judicial precedent, we conclude that the regulation does not exempt Fioricet from the application of 21 U.S.C. § 841(b)(1)(E) and 21 U.S.C. § 841(h).

By its own terms, 21 C.F.R. § 1308.32 (the "Regulation") provides an exemption strictly limited to the registration, labeling, packaging, record-keeping and security requirements delineated in a defined list of U.S. Code provisions. By implication, any statutory provision *not* expressly listed as an exemption applies with full force against Fioricet. None of those exempted provisions mentioned in the Regulation were charged in the case at bar. More to the point, the statutory provision under which Lasher was charged - § 841 - is not among those from which the Regulation exempts Fioricet. Nor, as defendant concedes, does the Regulation exempt Fioricet from the application of the Controlled Substances Act's other criminal statutes. Def. Mem. at 9; see also Gov't Opp. at 15-16. On the

contrary, the Regulation expressly limits its exemptions "for administrative purposes only."

Our holding is consistent with the only judicial precedent on point. In 2010, Judge Heaton of the Western District of Oklahoma issued a decision denying a motion to dismiss an indictment identical in large part to this one. United States v. Williams, No. 10 Cr. 216 (HE), 2010 WL 4669180 (W.D. Okla. Nov. 9, 2010). In Williams, the defendant pharmacy owner was charged with the criminal distribution by means of the internet of the same drug, Fioricet, in a scheme like the one charged here, in violation of the same statute charged here, 21 U.S.C. § 841. The defendant in Williams also moved to dismiss the indictment on the same grounds as those advanced by Lasher - i.e., that the Regulation's limited exemptions rendered Fioricet a non-controlled substance for the purposes of the indictment. Id. at *1. The Williams court denied the defendant's motion, reasoning, as we do here, that Fioricet's regulatory "exemption is expressly limited - 'for administrative purposes only,'" and that "[t]he regulation does not exempt the product from the application of Part D - Offenses and Penalties," which set forth the criminal provisions of the Controlled Substances Act, including, as relevant, the prohibition against the type of internet distribution charged in both cases. Id. The court's conclusion in Williams applies with equal force here: "Fioricet

remains a controlled substance despite being an exempted prescription product." Id.

Defendant's arguments to the contrary are unpersuasive. By law, a defendant seeking the protection of a regulatory exemption has the burden of establishing that the claimed exemption is applicable. 21 U.S.C. § 885(a)(1) ("It shall not be necessary for the United States to negative any exemption or exception . . . and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit."). Here, Lasher has failed to carry that burden.

Notwithstanding defendant's contentions to the contrary, the phrase "for administrative purposes only" does not introduce ambiguity. On its face, an exemption "for administrative purposes only" clearly cannot and does not encompass exemptions from the criminal laws. Whatever the precise connotation and ambit of the exemption "for administrative purposes only," the one meaning it cannot have is the one that Lasher now urges. Moreover, the statutory and regulatory framework make clear that administrative enforcement for violations of the Controlled Substantive Act is entirely separate and distinct from criminal prosecutions like this one. See 21 C.F.R. § 1301.41 ("Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or

any other law of the United States."); 21 U.S.C. § 847 ("Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.").

Defendant tries in vain to expand the ambit of the Regulation's exemption beyond the administrative realm. In one such effort, Lasher endeavors to bootstrap a reference to § 829 (one of the exempt sections) in a separate, uncharged subsection of § 841, the statute charged here, to argue that Fioricet should be exempt from the application of § 841 as a whole. Def. Mem. at 13. The Indictment, however, neither references nor charges the violation of § 829. This attempt to expand a single administrative exception into a wholesale exemption from criminal penalties fails.

Defendant's related argument that Fioricet cannot be a controlled substance because its packaging label lacks the "CIII" symbol denoting a controlled substance is similarly unavailing. As discussed, the Regulation exempts Fioricet from labelling and packaging requirements, which explains the absence of the "CIII" symbol. To assume that the labelling exemption precludes criminal prosecution is to beg the question.

Finally, Lasher's resort to the rule of lenity and the vagueness doctrine gains no purchase. These doctrines, grounded in due process considerations, are intended to ensure that a

prospective defendant has "fair warning" of conduct that is criminally proscribed. United States v. Lanier, 520 U.S. 259, 265-66 (1997). The "vagueness doctrine" prohibits enforcement if a statute is "so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application." Id. at 266 (quoting Connally v. General Constr. Co., 269 U.S. 385, 391 (1926)). The "rule of lenity" provides that if, and only if, a criminal statute is ambiguous, that ambiguity should be resolved "as to apply it only to conduct clearly covered." Id. (citing Liparota v. United States, 471 U.S. 419, 427 (1985); United States v. Bass, 404 U.S. 336, 347-348 (1971); McBoyle v. United States, 283 U.S. 25, 27 (1931)). For both doctrines, "the touchstone is whether the statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." Id.

Neither of these doctrines provide assistance to the defendant here. Because the statutory language is clear, the rule of lenity is inapplicable and no further evaluation of it must be made.² See Boyle v. United States, 556 U.S. 938, 950 (2009) ("Because the statutory language is clear, there is no

² Even assuming for the sake of argument that some ambiguity remained in the statutory language, the Court would be required to evaluate "the language and structure, legislative history, and motivating policies of the statute" as a precursor to the application of the rule of lenity. Moskal v. United States, 498 U.S. 103, 108 (1990) (citations omitted). We note without deciding that this analysis would almost certainly compel the same result.

need to reach petitioner's remaining arguments based on statutory purpose, legislative history, or the rule of lenity."); Salinas v. United States, 522 U.S. 52, 66 (1997) ("The rule [of lenity] does not apply when a statute is unambiguous or when invoked to engraft an illogical requirement to its text."). The Supreme Court further instructs, as relevant here, that "[n]o rule of construction . . . requires that a penal statute be strained and distorted in order to exclude conduct clearly intended to be within its scope." Salinas, 522 U.S. at 59 (citation omitted).

Regarding the vagueness doctrine, the "test does not demand meticulous specificity," but rather only requires that the statute, on an as-applied basis, "conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices." United States v. Coppola, 671 F.3d 220, 235 (2d Cir. 2012) (internal citations omitted). Here, any potential vagueness concerns are wholly allayed by at least three factors. First, the defendant, a highly trained pharmacist, operates in a heavily regulated industry and hence should reasonably be expected to inform herself of the relevant laws. See Village of Hoffman Estates v. The Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982) ("[E]conomic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face

economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action. Indeed, the regulated enterprise may have the ability to clarify the meaning of the regulation by its own inquiry, or by resort to an administrative process."). Defendant, as the pharmacist filling the prescriptions at issue, assumed a regulatory responsibility to ensure that any prescriptions for controlled substances were issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. 1306.04(a).

Secondly, where, as here, the statute contains a specific intent requirement, the Supreme Court "has recognized that a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." Village of Hoffman Estates, 455 U.S. at 499. Indeed, in a subsequent opinion addressing a motion to dismiss a superseding indictment substantively like this one, the Williams court found that, notwithstanding any confusion engendered by DEA Administrator statements regarding Fioricet, "[t]he specific intent requirement for the crimes charged saves the statutes from potential unconstitutionality." United States v. Williams, No. 10 CR 216 (HE), 2011 WL 4104654 at *4 (W.D. Okla. Sept. 14, 2011)

Third, as relevant to both lenity and vagueness doctrines, the Supreme Court precedent defendant herself cites specifies that a "judicial gloss on an otherwise uncertain statute" can provide the clarity necessary for fair warning, as long as no "novel" type of criminal enforcement is pursued where "neither the statute nor any prior judicial decision has fairly disclosed [the conduct] to be within its scope." Lanier, 520 U.S. at 266; see Def. Mem. at 14. Just such a clarifying "judicial gloss" existed in the form of the 2010 Williams opinion - the very type of "prior judicial decision" envisioned by the Supreme Court to put the defendant on notice that the specific activity charged was criminal in nature.

Thus, even though Fioricet is entitled to certain specific and limited administrative exemptions pursuant to the Regulation, it remains a controlled substance subject to the criminal statute charged here. Accordingly, defendant Lasher's motion to dismiss Counts One and Two is denied.

III. Counts Three and Four: Misbranding Offenses Adequately Alleged

In Counts Three and Four, the Indictment charges Lasher with misbranding offenses: conspiracy to misbrand prescription drugs in violation of 18 U.S.C. § 371 and the substantive crime of misbranding prescription drugs including Fioricet, as well as Soma and Ultram and their generic forms, in violation of 21

U.S.C. §§ 331, 333, and 353. Indictment ¶¶ 15-20. According to the governing statute, any prescription drug - not necessarily a controlled substance - is "misbranded" unless dispensed "upon a written prescription of a practitioner licensed by law to administer such drug" 21 U.S.C. § 353(b).

In short, defendant's challenge to Counts Three and Four emphasizes the absence of an articulated, statutory definition of the critical term "prescription." Defendant argues that, because the Food, Drug and Cosmetic Act does not, by its terms, explicitly require a face-to-face consultation to establish the validity of a "prescription," the internet pharmacy scheme alleged in the Indictment, even if true, does not state a crime. Def. Mem. at 16-17.

While defendant correctly notes that the statute provides no definition for the term "prescription," in cases such as this, case law has defined it "as one issued in the usual course of professional practice and for a legitimate medical purpose," originating from "a bona fide physician-patient relationship." United States v. Smith, 573 F.3d 639, 652 (8th Cir. 2009) (citation omitted). Whether the prescriptions filled here were issued in the usual course of practice, pursuant to a bona fide physician patient relationship, is a question to be argued before and resolved by the jury. Id. at 652-53. At this stage, however, because the Indictment adequately alleges that the

prescriptions were issued outside a bona fide physician patient relationship, the misbranding counts survive.

Defendant also contests the sufficiency of the government's allegations regarding her specific intent. Def. Mem. at 18-20. For the reasons discussed infra in Section IV, this argument fails.

IV. Remaining Counts: Specific Intent Adequately Alleged

Defendant's arguments as to Counts Five, Six, and Seven, charging mail and wire fraud conspiracy and money laundering conspiracy, can be resolved easily. For these Counts, as well as for Counts Three and Four, defendant contends that the government has failed to properly allege the requisite specific intent to defraud. Def. Mem. at 18-22. Nevertheless, because the Indictment tracks the language of the relevant statutes (see Indictment ¶¶ 17, 20, 23, 24, 28, 32) and adequately alleges the essential elements of the crimes charged, defendant's motion is denied. United States v. Wexler, 621 F.2d 1218, 1223 (2d Cir. 1980).

V. Motion to Strike Surplusage Reserved

Defendant's final request is to strike as surplusage the references to non-controlled prescription drug Ultram where it appears in Counts One and Four. Def. Mem. at 22-24. With regard to Count Four, which charges the substantive crime of misbranding, defendant argues that because Ultram was not

mentioned in any overt acts listed in Count Three, which charges conspiracy to misbrand, Ultram must not be relevant to the case writ large. Def. Mem. at 23-24. This claim is meritless. As the government points out, it is under no obligation to allege all of the overt acts taken in furtherance of a conspiracy. Gov't Opp. at 50. The absence of any given overt act in a conspiracy count has no bearing on whether that conduct is adequately alleged in a related substantive count. Id.

By contrast, defendant makes a somewhat more persuasive parallel argument that the Indictment's reference to Ultram in Count One could be "inflammatory and prejudicial." United States v. Scarpa, 913 F.2d 993, 1013 (2d Cir. 1990) (citation omitted). She rightly points out that the dispensing of non-controlled substances like Ultram is irrelevant to the offense of narcotics conspiracy charged in Count One, and hence carries the potential for juror confusion or prejudice. Def. Mem. at 22-23. At oral argument, however, the government clarified that any potential confusion or prejudice was inadvertent and merely a consequence of the manner in which Indictments tend to describe in the first count the full scope of the scheme charged in subsequent counts. Tr. at 31-33.

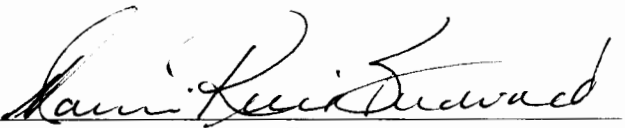
Because the appearance of Ultram in Count One appears to be merely a function of the placement of background information, we need not reach a decision as to defendant's motion to strike at

this time. Rather, with the consent of defense counsel, we will revisit the issue if and when this case progresses to a point at which the concerns raised by defendant regarding prejudice and jury confusion are more immediate. Tr. at 33.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss the Indictment is denied. The Court reserves decision on the motion to strike surplusage from the Indictment.

Dated: New York, New York
August 20, 2014



NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE